Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Different requirements for Phase I Investigational Drug Products: which GMPs apply since most Phase I drugs are exempt from full GMP requirements and what IND data requirements are necessary as a result?

Boston, MA

March 1st & 2nd, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Stephanie Cooke

President/CEO, Cooke Consulting Inc.

Stephanie Cooke, is the President/CEO of Cooke Consulting, Inc. Stephanie uses her roughly 20 years of experience to provide global consulting services in various areas of Regulatory Affairs, Quality Assurance and validation for pharmaceutical, biological/biotech products, medical device, combination drug/device and nutraceutical firms. Her broad-based experience includes preparation of regulatory dossiers for human and animal pharmaceutical (chemical entities and biologically-based drugs), biotech products, drug/device combination

Overview:

In January 2006, FDA issued a final rule which specified that most pharmaceutical products (including biologics) produced for use in Phase I clinical trial studies were exempted from complying with GMP requirements, as defined in 21 CFR Part 211 under 21 CFR 210.2©. Section 501(a)(2)(B) of the FD&C Act requires drugs, including IND products, to comply with cGMPs or if they are not manufactured in compliance with cGMPs, they are deemed adulterated. Based on this statutory requirement for manufacturers to follow GMPs, FDA issued cGMP regulations for drug and biological products in the Code of Federal Regulations (in 21 CFR parts 210 and 211).

Agenda:

Day One

Lecture 1 (90 Mins) :

30 Minutes: brief overview of the objectives of the seminar, brief introduction of attendees, including their functions, type of products that they are working on (if applicable), and the function(s) they serve.

60 Minutes: an explanation of the statutory requirements, the changes that precipitated the products being exempt and the speciific products exempt and those that were not exempt will be discussed.

Lecture 2 (90 Mins) :

Brief discussion of the product lifecycle, including when regulatory filings, such as the IND and NDA (or the equivalent, depending on region) are filed, description of differences in chemically-synthesized drug and biologic products and biotech products will be briefly discussed. Brief discussion of the Pharmaceutical Quality System, as per ICH Q10 (and the companion documents, ICH Q8, pharmaceutical development and ICH Q9, quality risk management, will be introduced.

Lecture 3 (90 Mins) :

15-30 Minutes: brief discussion of GMPs for APIs, specifically the information that addresses GMPs for products in clinical trials, ICH Q7. GMPs for phase I investigational drug products will be dsicussed, including guidance for complying with the statute, discussion of having appropriate QC procedures in effect during product development to ensure the quality and safety of the investigational drugs are maintained, as well as emphasis on following appropriate GMPs, as both of these actions will facilitate the manufacture of equivalent of comparable IND product for future clinical trials. Several different resources/technologies are suggested to facilitate conformance with cGMPs and to streamline product development.

Lecture 4 (90 Mins) :

Additional review of GMPs for phase I investigational drug products, including personnnel, QC function, facility and equipment, control of components, and containers and closures, manufacturing and records, laboratory controls, including testing and stabilit, packaging, labeling and distributing and recordkeeping will be addressed. If we do not get through all of the information just mentioned in this time period, the dicussion will continue the following day, along with the remaining content that needs to be understood for implementing GMPs for Phase I Products.

Day Two

Lecture 1 (90 Mins) :

Continued discussion of GMPs for Phase I Investigational drug products, including content from previous day and the special manufacturing situations, such as multi-product facilities.

Lecture 2 (90 Mins) :

Continued discussion of GMPs for Phase I Investigational drug products to include considerations and adventitious agent control will be addressed in regards to biological and biotechnological products. Gene therapy and cellular therapy products will be addressed, as well as sterile products/aseptically processed products. The remaining time will introduce "INDs - Approaches to complying with CGMP during Phase I".

Lecture 3 (90 Mins) :

The IND Regulation(21 CFR 312.23(a)(7)(i)) will be reviewed, including the "sufficient CMC information to ensure the proper identification, quality, purity, and strength of the investigational drug." Each item (identification, quality, purity, and strength of the investigational drug) will be reviewed, including meaning of each, some of the requirements, such as strength and assays for drug substance and drug product, validation requirements of each, blend uniformity, uniformity of dosage units, container/closure, stability, etc. If additional time is left, will start review of CMC regulatory requirements.

Lecture 4 (90 Mins) :

The CMC regulatory requirements, including requirements for drug substance (APIs) and drug products. Potential safety concerns for an investigational drug product (and its drug substance) will be discussed in order to help attendees avoid safety issues and clinical holds. Other potential hold issues will be addressed, including impurities, expiration dating, etc. will be addressed. The ICH guidance documents specific for identity, stability, etc. will be provided to the attendees. Questions will be accepted throughout the seminar, but any questions that the attendees have and discussions are encouraged to ensure that all attendees have any questions answered.

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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